

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

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)  
) MDL No. 1456  
)

) CIVIL ACTION: 01-CV-12257-PBS  
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THIS DOCUMENT RELATES TO  
ALL CLASS ACTIONS

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) Judge Patti B. Saris  
)  
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) **[FILED UNDER SEAL]**  
)

**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF CLASS CERTIFICATION**

**[REDACTED VERSION]**

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## I. INTRODUCTION

Defendants' massive filing fails to provide a legal or factual basis to deny class certification.

In the First Circuit, a class is appropriate if "a sufficient constellation of common issues binds class members together." Defendants' conduct, in publishing artificially inflated AWP, which were then uniformly used in the reimbursement process by the proposed Class, creates such a constellation. The question of whether Defendants engaged in the unlawful inflation of any AWP will be adjudicated by evidence (*e.g.*, form contracts, industry documents, expert analysis) that is common to all members of the proposed Classes. Such commonality is sufficient to invoke the procedural device of class certification, a judicial and administrative tool far superior to the hundreds or thousands of redundant trials Defendants must be implicitly arguing as the alternative.

As to the original Medicare Part B Class<sup>1</sup> – *i.e.*, consumers and third-party payers who overpaid the Medicare 20% co-insurance – Defendants have failed to raise any facts, which materially refute Plaintiffs' ability to prove their case on a common basis. Indeed, by statute, Part B drugs are not subject to "negotiations" or the "complexity" that Defendants claim exists elsewhere, and therefore common issues clearly predominate. Moreover, nor does the application of state law to the claims of the Medicare Part B Class undermine predominance, both because one state's law may apply nationwide and because varying state law damage remedies are "rarely determinative under Rule 23(b)(3)." *Smilow v. Southwestern Mobile Sys.*, 323 F.3d 32, 40 (1st Cir. 2003).

As for Class members who over-reimbursed providers due to Defendants' inflation of the AWP for oncology and other physician-administered drugs – *i.e.*, those consumers and third-party payers who are now under the umbrella of the amended Physician-Administered Class –

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<sup>1</sup> With this memorandum Plaintiffs have filed a motion to amend the class definitions. In this brief, Plaintiffs will use the nomenclature of the class re-groupings used in that motion for the three proposed classes of the "Physician-Administered Class," the "Self-Administered and Speciality Pharmacy Class" and the "RICO Payer Class."

Defendants' claims of complicating individual factual issues fade upon examination. In order to be included in the Class, these private reimbursements must be based on a contract using AWP as a benchmark. All parties have shown great ease in identifying these AWP-based contracts. In addition to Dr. Hartman's analysis, the only empirical study of reimbursement for physician-administered drugs, the Dyckman study, found that *all* plans reimbursed for such drugs based on AWP. Again, such uniform use of AWP is exactly why a class is appropriate here. Since these contracts ultimately manifest themselves in a formulaic reimbursement based on AWP, proof of Plaintiffs' claims and other trial issues affecting the existence and size of over-reimbursement for physician-administered AWPIDs will be based predominantly on a common proof.

As for self-administered drugs – *i.e.*, the class of consumers and third-party payers whose contracts use the AWP benchmark and, as a result over-paid PBMs or pharmacies for oral or topical AWPIDs – Defendants' claim of "complexity" of the industry fails. Defendants ignore the commonality created by the use of AWP as an "industry standard" and the evidence demonstrating that all third-party payer reimbursement is "anchored" off AWP.<sup>2</sup> AWP as the "standard" or "anchor" is confirmed by the absolute uniformity of the contracts between plans and PBMs, and PBMs and pharmacies. AWP is the basis for reimbursement in almost every single one of these contracts. As a result, if the AWP has been artificially inflated due to Defendants' scheme, all Class members using AWP as a benchmark suffer impact, and that impact can be proven using standard econometric techniques. Adjudication will involve evidence common to all Class members.

As for superiority and manageability, Defendants rely on irrelevant mass tort cases, yet ignore the recent string of authorities certifying RICO cases and finding a class action to be superior even if follow-on proceedings regarding causation and damages are required.<sup>3</sup> These

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<sup>2</sup> See Ex. 1 (AZ0565611-14 at 612). All exhibits referenced in this memorandum are attached to the Reply Declaration of Steve W. Berman ("BRD") unless otherwise indicated.

<sup>3</sup> See *Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004); *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656 (7th Cir. 2004).

recent opinions – *Carnegie*, *Humana* and *IPO*<sup>4</sup> – hold that size and complexity do not mandate denial of class certification. Though Defendants repeatedly attempt to scare this Court into believing that this case is too massive and therefore unmanageable, the *IPO* court, in certifying a similarly large and complicated case, faced the challenge: “Trying these cases will be an arduous task, but that is no reason to close the courthouse door to the alleged victims of a sophisticated and widespread fraudulent scheme.” *Id.*, at \*5-6.

## II. DEFENDANTS LARGELY IGNORE THE STANDARDS FOR CLASS CERTIFICATION

In their brief in opposition to class certification, Defendants largely ignore the legal standard applicable on a Rule 23 motion. In a recent landmark decision certifying several classes in the *IPO* litigation, Judge Scheindlin exhaustively reviewed the standards for ruling on a class motion. Like this circuit, the Second Circuit requires liberal construction of Rule 23, and the *IPO* court noted that “to deny a class action simply because all of the allegations of the class do not fit together like pieces in a jigsaw puzzle would destroy much of the utility of Rule 23.” *Id.*, at \*71-72. After reviewing the jurisprudence concerning Rule 23 standards, the court ruled that a court may not weigh conflicting expert testimony. Instead, the sole job of a district court “is to ensure that the basis of the [plaintiff’s] expert opinion is not so flawed that it would be inadmissible as a matter of law.” *Id.*, at \*83. The court found that to pass muster under Rule 23’s “rigorous analysis test,” a plaintiff must make “some showing” that the requirements of Rule 23 have been satisfied. The showing may take the form of evidence, allegations or expert opinions. *Id.* Here, using expert testimony and other evidence, Plaintiffs have made such a showing.

## III. PLAINTIFFS HAVE OFFERED A METHODOLOGY FOR PROVING CAUSATION AND DAMAGES ON A CLASS-WIDE BASIS

Plaintiffs have made far more than “some showing” that each claim is capable of common proof.

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<sup>4</sup> See *In re Initial Pub. Offering Sec. Litig.* (“*In re IPO*”), 2004 U.S. Dist. Lexis 20497 (S.D.N.Y. Oct. 13, 2004).

First, Plaintiffs can establish through common proof that AWP was the basis for reimbursement for each Class member. For the Part B Class, by regulation, drugs were priced and reimbursed based on AWP.<sup>5</sup> Defendants contend that physician-administered drugs are not reimbursed based upon AWP. Deposition testimony,<sup>6</sup> expert analysis and other studies show otherwise.<sup>7</sup> As for self-administered and physician-administered drugs, Defendants' own documents prove beyond any doubt that AWP was the "industry standard," and that "payers use AWP as a basis for reimbursing retail pharmacies," [REDACTED] for reimbursement. As a result, any increases in AWP will increase the spread and the amount paid by Class members.<sup>8</sup>

Plaintiffs can prove this industry standard through the introduction of contracts at every level of the distribution chain that uniformly use AWP as the basis for payment.<sup>9</sup> An examination of the 1,200-plus contracts produced in the litigation reveals that virtually *every* contract utilizes AWP as a basis for reimbursement.<sup>10</sup> Indeed, senior industry executives recently testified before Congress that AWP was "codified" for use in the public sector and "by contract" in the private sector.<sup>11</sup> This uniformity, or "codification," of the use of AWP by each Class is supported by deposition testimony from health plans, their consultants and PBMs as to the standardized use of AWP and its perceived reliability as a negotiating benchmark.<sup>12</sup> This evidence comports with Dr. Hartman's opinion that AWP is the "single publicly available list

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<sup>5</sup> Hartman Rebuttal Declaration ("HRD") at ¶ 21(b), p. 22. Rosenthal Tutorial at pp. 5-8; Hartman Decl., Attachment D.

<sup>6</sup> App. 1(h). All references to "App." are to appendices compiled in Plaintiffs Appendix of Summary Charts in Support of Class Certification submitted with this brief.

<sup>7</sup> HRD at ¶ 33(c), p. 46; Dyckman Study, Ex. 14 to Rosenthal Tutorial. For example, an analysis of the terms in contracts for physician-administered drugs cited by Young reveals that *all* are based on AWP. See App. 1(k).

<sup>8</sup> BRD Ex. 1 (AZ 0565612).

<sup>9</sup> See BRD Exs. 2-3 (summary charts of typical contract language confirming the ubiquity of AWP).

<sup>10</sup> See HRD at ¶ 22, p. 26 (referring to an analysis of more than a thousand contracts produced in the case).

<sup>11</sup> See BRD Ex. 4 (Statement of Edward Stratemeier before U.S. House Subcommittee dated December 7, 2004).

<sup>12</sup> See App. 1(a) and App. 1(b) (summarizing deposition testimony regarding the reliability of AWP and its use as a reimbursement benchmark). See also BRD Ex. 5 (Testimony of David Joyner, Executive Vice President of Caremark, one of the major PBMs. "I know of no other pricing source that is as comprehensive and accepted across the industry as AWP" cited in HRD at ¶ 25, p. 32).

price that is the basis for the preponderance of all negotiations.”<sup>13</sup> To defeat this strong showing of commonality, Defendants are forced to falsely claim that AWP was not the basis for reimbursement. To the contrary, the facts are so strong otherwise that even Mr. Young must admit that AWP “was used to express the reimbursement benchmark.”<sup>14</sup> Deposition testimony from health plans, consultants and PBMs confirms this.<sup>15</sup>

Second, Plaintiffs can prove through deposition testimony, contracts and expert opinion, that because AWP is the “starting point” for prescription drug reimbursement” it follows that if “the starting point for prescription drug reimbursement is artificially inflated, the resulting reimbursement rates paid are also artificially inflated.”<sup>16</sup>

Plaintiffs will also introduce expert testimony based upon economic analysis that although some Class members knew that AWP was greater than acquisition cost, “no one knew that the AWPs were grossly inflated” relative to such costs.<sup>17</sup> Defendants’ tutorial expert admitted as much when, confronted with examples of specific spreads of [REDACTED] to [REDACTED] during cross-examination, he could not identify any Class members with knowledge of such spreads.

Dr. Hartman has provided a “methodology that accounts for variability” and allows accurate calculation for class-wide liability, causation and damages.”<sup>18</sup> This is not surprising given that Young admits a prevailing range of reimbursement at “AWP – 14% to 18%,”<sup>19</sup> an

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<sup>13</sup> HRD at ¶ 16(d), p. 15; *see also* App. 1(m) at pp. 1-12 citing testimony omitted from Young materials regarding use of AWP by Class members.

<sup>14</sup> Young Decl., ¶¶ 133-34.

<sup>15</sup> App. 1(b); HRD at Attachment C.1.

<sup>16</sup> HRD at ¶ 3(d), p. 4, ¶ 14(a)-(d), ¶ 24(d), p. 31.

<sup>17</sup> HRD at ¶¶ 50-57, 60, pp. 63-68, 70. *See also* App. 1(d) (summarizing testimony of Class members’ lack of knowledge of actual spreads). *See also* App. 1(f) (lack of knowledge of extent of rebates and discounts and other offsets).

<sup>18</sup> HRD at ¶ 38, pp. 49-50. All of the “variations” put forth by Defendants have produced in reality a tight bond – discounts of 14% to 18% of AWP. Such variations are not only minimal, they are typical of any market. If such variations precluded class certification and trumped the use of standard formulaic methodologies, few classes would be certified.

<sup>19</sup> Young Decl., ¶ 134.

extremely narrow range that supports use of Dr. Hartman's yardsticks, and a but-for AWP to establish class-wide impact.<sup>20</sup>

Using flawed economic methodology, Defendants attempt to defeat predominance by asserting that the data show that claims reimbursements vary wildly and are not tied to AWP.<sup>21</sup> However, proper economic analysis demonstrates that AWP and reimbursement are linked. Dr. Hartman found that there is an "obvious demonstrable positive relationship between reimbursement rates and AWP," for brand name,<sup>22</sup> generic<sup>23</sup> and physician-administered drugs,<sup>24</sup> and provides a method for doing so on a class-wide basis.

Defendants quarrel with Dr. Hartman's proffered methodology of providing common evidence (through economic data and opinion testimony) as proof of causation and aggregate damages, and they claim it depends upon an individual analysis of each Class member's "expectations" and "negotiations." This is not true. Dr. Hartman will establish a benchmark beyond which the AWP was inflated. This is not a subjective standard as Defendants portray it. Rather, that benchmark will be based on evidence and techniques relied upon by economists (which Mr. Young, Defendants' principal expert is not) and is an objective standard based on quantitative analysis.<sup>25</sup> Purchases at prices above that benchmark establish impact for all members of the Class purchasing that specific drug at a price deemed to be inflated by Dr. Hartman's model. Where behavior artificially raises the price of a product that is used

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<sup>20</sup> HRD at ¶ 41, p. 51. As Dr. Hartman explains, Young admits that despite "all of the variables" and the thousands of negotiations defendants claim exist in the market, "payors expressed their pharmacy reimbursement based on formulas that include a discount off AWP between [REDACTED]." Young in essence admits that reimbursement rates all reference AWP, are tightly clustered, that there is no real negotiation involving AWP and this cluster is within the range of Dr. Hartman's yardsticks.

<sup>21</sup> HRD at ¶¶ 29-31, pp. 33-38 (describing fundamental flaws in defendants' analysis).

<sup>22</sup> HRD at ¶ 22, pp. 27-28. Dr. Hartman analyzed actual claims data to determine the frequency claims were paid by Harvard Pilgrim Health Care with reference to AWP. Among the sample looking at branded drugs, [REDACTED] were paid by reference to AWP. For generics, [REDACTED] were paid with reference to AWP. HRD at ¶ 22(c), p. 27. Hartman then demonstrates how this can be done for other class members where he achieved similar results. HRD at ¶ 22(h)-(i), p. 29-30.

<sup>23</sup> HRD at ¶ 32(d), pp. 39-41; ¶ 33(b), pp. 44-46.

<sup>24</sup> HRD at ¶ 33(c), p. 46, Attachment D. Dr. Hartman describes how reimbursements for physician-administered drugs track the AWP, and using Zoladex as an example, and observes the same pattern of overcharge as in the government action involving Lupron. *See also* HRD at ¶¶ 34-35, pp. 47-48, applying a regression analysis and finding a statistically significant relationship between AWP and reimbursement.

<sup>25</sup> HRD at ¶ 44(b), p. 58 (method follows standard economic methods). *See also* Section V at pp. 60-70.



throughout an industry, courts have allowed proof of liability and damage on a class-wide basis.<sup>26</sup> And Defendants, having taken hundreds of depositions, can prove not surprisingly, knowledge of a spread between AWP and WAC, but cannot prove Class members' knowledge of "expectations" of spreads in excess of the Hartman liability threshold benchmarks. Thus, Defendants' "expectation" defense, when carefully examined, fails. Likewise, Defendants' individual "negotiation" defense is unavailing. With 65,000 drugs in the marketplace, there is no meaningful drug-by-drug "negotiation" of AWP by members of the Class. This is also borne out by the cluster, in over a thousand contracts produced in the case, of discounts off of AWP, which Defendants' own experts admit, are in the "[REDACTED] range."<sup>27</sup> This tight cluster belies the notion of "expectations" or "negotiations" that Defendants contend eliminate common issues, and confirms that members of the Class viewed AWP as a reliable market signal.<sup>28</sup>

Defendants' position regarding the need for millions of individual inquiries also ignores a basic theory of economics of "revealed preferences," that suggests that economic agents indicate what information they relied upon by their behavior. In this case, the revealed preferences result in a cluster of contracts at AWP – [REDACTED], which reveals class-wide expectations that the spread between AWP and AAC was between 19% to 23% below AWP.<sup>29</sup> Dr. Hartman's analysis demonstrates that all members of the Class, even those with "bargaining power," continued to pay within the range of AWP-[REDACTED], which in turn, as a matter of economic analysis, indicates a class-wide absence of knowledge of the AWP scheme.<sup>30</sup> And the deposition testimony shows no knowledge of spreads in excess of the Hartman benchmarks.<sup>31</sup> Nor is there

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<sup>26</sup> See summary of cases cited in Appendix A attached hereto.

<sup>27</sup> Young, ¶ 134. See also ¶ 138, where Young admits that a survey of 535 employers found an average discount of AWP-14%.

<sup>28</sup> HRD at ¶ 46, pp. 60-61.

<sup>29</sup> HRD at ¶¶ 41, 49-52, pp. 62-64.

<sup>30</sup> HRD at ¶¶ 49-52, pp. 62-64; HRD footnote 87, p. 61. See also Young Decl., ¶¶ 134, 138 (confirming range of discounts).

<sup>31</sup> App. 1(d).

evidence that members of the proposed Classes were aware of the size of spreads being created by Defendants.<sup>32</sup>

Thus Plaintiffs can prove on a class-wide basis the predominance of AWP as an element of pricing, the common question of what the price would have been but for the AWP scheme, and the impact of the scheme on the Class on a defendant-by-defendant, drug-by-drug basis.<sup>33</sup>

#### IV. PLAINTIFFS' SELF-ADMINISTERED DRUG CLASSES SATISFY RULE 23(b)(3)

##### A. At Any Trial, Proof Of Defendants' Wrongdoing Will Be Common To All Members Of the Self-Administered Drug Classes

In their opening brief, Plaintiffs identified an overwhelming number of issues to be proved by evidence of Defendants' conduct that is common to each and every member of the Class. This includes each element of Plaintiffs' claim that Defendants: (1) conducted, (2) an enterprise, (3) through a pattern (4) of racketeering activity. *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985); *see* Opening Br. at 23-26. Plaintiffs set forth, in detail, how Defendants' conduct of an enterprise, Defendants' "pattern" of racketeering activity, Defendants' racketeering acts, and proximate causation each can be proven through evidence common to all Class members. *Id.*

Defendants do not contend to the contrary but instead try to shift the focus to alleged individualized issues. In and of itself, this concession is sufficient to require class certification here. The decision in *In re Synthroid Mktg. Litig.*, 188 F.R.D. 295 (N.D. Ill. 1999) is directly on point and squarely rejects the very argument Defendants make here. As the *Synthroid* court held in certifying a claim under RICO and state consumer statutes, "[t]he question of liability ... will turn on whether the defendants engaged in the alleged conduct. . . ." *Id.* at 300; *see* Opening Br.

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<sup>32</sup> App. 1(f). HRD at ¶ 60, p. 70. Tellingly, Defendants, having conducted dozens of depositions never once confronted a witness with the ASP data in the Hartman Declaration and asked, for example, of their knowledge that the spread on Vepesid was [REDACTED], Coumadin as high as [REDACTED], or Schering's Theophylline as high as [REDACTED]. *See* Hartman Decl., Tables 2 & 3. The public reports that Defendants' latch onto do not demonstrate such knowledge. First, none of the reports discusses marketing of the spread to change providers' presumption patterns. Second, for the few branded drugs discussed in the reports, the discounts are usually 12% to 17%. *See, e.g.*, App. 1(l), page 1. Third, with few exceptions, all drug discounts mentioned in the reports are within the Hartman yardsticks and the discounts in the reports are in line with those in the contracts that are being used in the industry.

<sup>33</sup> HRD at ¶ 14, pp. 9-13; ¶¶ 52-55, 57, pp. 63-65, 68.

at pp. 27-29. In establishing liability, the focus is on Defendants' conduct in (a) publishing or causing the publication of AWP's that were deceptive and/or fraudulent; (b) using those AWP's as a basis to increase market share; and (c) the resulting artificial inflation of reimbursement. It is these core acts that establish predominance.

In analyzing predominance, courts have focused on a defendant's conduct and not that of individual class members.<sup>34</sup> Confirming the validity of the line of cases cited in Plaintiffs' opening memorandum on this point (pp. 27-28), the Third Circuit recently found the predominance test satisfied where a drug company had engaged in a campaign to deceive consumers that generic Warfarin was not equivalent to Coumadin. Noting that the Supreme Court in *Amchem*<sup>35</sup> held that the predominance test is readily met in cases of consumer fraud, the court found the predominance test satisfied because liability focused on the conduct of the manufacturer defendant and not that of individual class members. *See In re Warfarin Sodium Antitrust Litig.*, 2004 U.S. App. Lexis 25180 (3d Cir. Dec. 8, 2004).

*Weil v. Long Island Sav. Bank, FSB*, 200 F.R.D. 164, 175 (E.D.N.Y. 2001), is also instructive. In *Weil*, the plaintiffs claimed that the bank, its president and law firm charged excessive legal fees in violation of RICO. Defendants argued that individual issues predominated because the degree of reliance among class members differed based on testimony that some borrowers obtained mortgages despite being advised that the Defendant's legal fees were higher than those charged by other banks. *Id.* at 175. Although reliance applies to RICO claims brought in the Second Circuit (unlike here), the court held that individual issues relating to reliance did not predominate because the focus of the inquiry was on the common question of liability. Common questions predominate because each potential class member was allegedly defrauded by the same scheme. *Id.* at 176. "[D]efendants' argument that some of the potential plaintiffs may have negotiated lower legal fees will not defeat class certification. This issue,

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<sup>34</sup> See, e.g., a comparison of common questions found by the IPO court sufficient to warrant certification with common present questions in AWP. Appendix B attached hereto.

<sup>35</sup> *Amchem Prods. v. Windsor*, 521 U.S. 591, 625 (1997).

which relates primarily to damages, does not render the class action valueless.” *Id.*<sup>36/37</sup> The same is true here with respect to Defendants’ “negotiations” argument. The focus is on Defendants’ unlawful scheme, not the individual negotiations of its intended victims.

**B. Defendants’ Purported Individual Causation Arguments As To Self-Administered Drugs Are Red Herrings That Ignore The Record Evidence**

Defendants’ insistence that each and every Class member must be examined individually to determine “what each class member knew and when he, she or it knew it” totally misconstrues Plaintiffs’ claims and ignores binding First Circuit and other persuasive precedents.

First, as already discussed, reliance is not an element of federal RICO or any of the state unfair and deceptive trade practices claims.<sup>38</sup>

Second, “[p]laintiffs need only come forward with plausible statistical or economic methodologies to demonstrate impact on a class-wide basis.” *Humana*, 382 F.3d at 1259. Dr. Hartman’s but-for analysis – which is a standard approach in economic analysis – will accomplish this. *See, e.g., In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 698-99 (S.D. Fla. 2004) (finding that Dr. Hartman’s analysis provides a reasonable basis for concluding that class-wide injury could be shown on a class-wide basis); *In re Visa Check/Master Money Antitrust Litig.*, 192 F.R.D. 68, at 82-83 (E.D.N.Y. 2000) (defendants’ individualized causation arguments “pass in the night” by plaintiffs’ expert’s but-for theory which posits class-wide injury resulting from each class member’s overpayment); *Bogorian v.*

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<sup>36</sup> “[T]he inquiry necessarily focuses on defendants’ conduct, that is, what defendants did, rather than what plaintiffs did.” *In re Flat Glass Antitrust Litig.*, 191 F.R.D. 472, 487-88 (W.D. Pa. 1999); *George Lussier Enters. v. Subaru of New Eng., Inc.*, 2001 U.S. Dist. Lexis 12054 (D.N.H. Aug. 3, 2001). The question of liability “will turn on whether the defendants engaged in the alleged conduct ..., not on the individual decisions and circumstances of countless people along the chain of distribution ....” *Synthroid*, 188 F.R.D. at 300.

<sup>37</sup> Similarly, in *Peterson v. H&R Block Tax Servs.*, 174 F.R.D. 78 (N.D. Ill. 1997), consumers filed a class action against their tax preparer for inducing them to pay for tax-related services that the defendant knew plaintiffs could not receive. Although reliance was not a required element of the plaintiffs’ claims in the Seventh Circuit, the defendant argued that individual issues of reliance predominated where class members who read and understood certain standard disclosure language could not claim to have relied on any misrepresentations. *Id.* at 84. The court disagreed, holding that “variations in individual reliance do not defeat certification because a scheme to defraud ... violates RICO regardless of the characteristics of the scheme’s intended victims.” *Id.* Even assuming that reliance was relevant, the court found that “it is well-established that individual issues of reliance do not thwart class actions,” and courts will presume reliance when it is logical to do so or when the allegations make reliance apparent. *Id.* at 84-85.

<sup>38</sup> *See, e.g., System Mgmt. Inc. v. Loiselle*, 303 F.3d 100, 104 (1st Cir. 2002) (no reliance under RICO).

*Gulf Oil Corp.*, 561 F.2d 434, 454 (3d Cir. 1977) (If the price structure in the industry is such that nationwide the conspiracy affected prices at the wholesale level fluctuated within a range, though different in different regions, was higher in all, the Court may presume Class-wide injury.).<sup>39</sup> This is precisely the methodology used by Hartman, which is based upon the uniform use of AWP.<sup>40</sup>

Third, whether a Plaintiff or Class member was aware that drugs could be purchased for a price less than AWP is irrelevant. The point is that, for every Class member, AWP was the common benchmark that determined the costs borne by that Class member minus a discount.<sup>41</sup> The fact that discounts cluster around a narrow range is evidence of lack of information as to the true nature of the spread. The uniformity of such discounts creates an economic objective indication of a complete lack of “expectation” that the spreads greatly exceeded AWP-14% to 18% for brand name drugs. For payers who made reimbursements based on AWP, they would have negotiated better deals than the single or low double-digit price discounts they could achieve had they known that the AWPIDs were wildly inflated.<sup>42</sup>

Fourth, Defendants’ arguments echo those rejected by the court in *Chisolm v. TranSouth Fin. Corp.*, 194 F.R.D. 538, 563 (E.D. Va. 2000), a civil RICO, consumer protection and common law fraud where defendants argued that they would need to “inquire into the situation of each putative class member, subjecting each to cross-examination and discovery,” with the end result being “an endless string of mini-trials.” *Id.* at 557. The court disagreed, finding that the very fact that class members made deficiency payments after repossession constituted

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<sup>39</sup> See also Appendix A attached hereto listing authorities applying similar analysis.

<sup>40</sup> See HRD at Section F (explaining proof of impact using standard econometric techniques); see also HRD Figures 1-A through 1-C.

<sup>41</sup> See HRD at ¶ 45. The differing expectations as to the precise definition of AWP does not detract from the predominance of common questions because “whatever their understanding, AWP was still the benchmark from which their reimbursement negotiations were fully referenced and the fact that all members of the class relied on AWP as an accurate market signal is evidenced by its uniform use in contracts.”

<sup>42</sup> See *In re IPO*, 2004 U.S. Dist. Lexis 20497, at \*116 (finding that had investors known that the alleged scheme had artificially inflated the price of the stock, they would not have retained their shares for any length of time after the stock’s immediate price gain); *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 168 n.19 (D. Mass. 2003) (noting the “difference between a sticker price and a sucker price”); *c.f. Peterson v. H&R Block Tax Servs., Inc.*, 174 F.R.D. 78 (N.D. Ill. 1997) (courts presume reliance when it is logical to do so or when the allegations make reliance apparent); *Humana*, 382 F.3d at 1259 (circumstantial evidence that is common to the whole class can be used to show reliance); HRD n.87, p. 61.

circumstantial proof of reliance. *Id.* at 560-62. Thus framed, the issue of whether their reliance was reasonable was an objective inquiry common to the entire class: “To conclude otherwise would deny human nature, run counter to the traditional presumption in favor of actors operating under rational economic choice, and leave the Court with an absurd conclusion.” *Id.* at 561 (emphasis added).<sup>43</sup>

Although reliance is not a requirement under any of Plaintiffs’ claims, the rationale espoused by *Chisolm* nonetheless applies. Rational economic choice dictates that third-party payers would not have agreed to use AWP as the pricing benchmark in their contracts – which are *all* based on AWP – had they known of Defendants’ fraud.<sup>44</sup> Furthermore, mere knowledge of the availability of discounts in the marketplace does *not* reveal the fraud unless Class members were aware of what everyone else was paying – and they were not, particularly given the lengths to which Defendants went to maintain the confidentiality of their pricing data.<sup>45/46</sup> In fact, and notwithstanding Defendants’ service of over 100 subpoenas on third-party payers and consultants and the plethora of depositions that Defendants have taken, ***Defendants cannot identify a single plaintiff or putative Class member who knew that Defendants intentionally inflated AWPIDs in order to impact drug usage patterns.***<sup>47</sup> To the contrary, the depositions

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<sup>43</sup> The court concluded that, even though the three subclasses reflected different theories of liability and an individualized computation of damages, the subclasses all alleged liability stemming “from the one common pattern of activity – the churning scheme that anchors this litigation.” Therefore, “a proper jury charge combined with a well-reasoned special verdict sheet and judicial assistance, if required pursuant to Federal Rule of Civil Procedure 53,” made “treatment of these claims under a single, consolidated class action ... superior to any other form of proceeding.” *Id.* at 569.

<sup>44</sup> HRD at ¶¶ 33-54, 59, 60. While class members held varying bargaining strengths when negotiating discounts, as Young admits, all payers expressed reimbursement based upon AWP and thereby revealed their expectations as to the range of appropriate discounts. The difference between expectations and reality is depicted in Figures 1A through 1C of HRD. See HRD at ¶¶ 53-54.

<sup>45</sup> HRD at ¶ 56, pp. 65-67. Explaining lack of transparency concerning true AAC or ASP.

<sup>46</sup> See *In re IPO*, 2004 U.S. Dist. Lexis 20497, at \*114 (knowledge that commissions were paid was not equivalent to alleging that “it was common knowledge that the price of stock was artificially inflated through illegal tie-in arrangements that required a large percentage of allocants to pay undisclosed compensation and to agree to make a certain number of purchases in the aftermarket at escalating prices in order to obtain an allocation”).

<sup>47</sup> Indeed, Gaier conceded that defense counsel never asked a single deponent whether he or she knew that Defendants marketed the spread or that Defendants intentionally inflated the AWP for the purpose of shifting market share. BRD Ex. 6 (Gaier Dep. at 324-25). Nor have Defendants shown any deponent the spreads depicted in the Hartman Decl., and asked if they would have utilized AWP – 14% if they had known the spread was [REDACTED] on Vepesid or used AWP – 50% if they knew the spread on Theophylline was [REDACTED]. See Hartman Decl., Tables 2 & 3.

taken and documents gathered to date demonstrate that market participants believe that AWP is a consistent and reliable benchmark for use in negotiating drug pricing.<sup>48</sup> Therefore, Defendants' argument that individual inquiries must be made into what "everyone knew" is but one "woven entirely out of gossamer strands of speculation and surmise" that should not be permitted "to tip the decisional scales in a class certification ruling." *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 298 (1st Cir. 2000). Simply put, if Defendants inflated AWP, a Class member was damaged without regard to the frequency and range of price concessions that they obtained (via discounts from AWP, rebates, or otherwise) because all Class members made drug reimbursements based on AWP – it was *the* substantial factor in causing the harm, which is the proximate cause test that applies in this Circuit.<sup>49</sup>

## V. PLAINTIFFS' PROPOSED PHYSICIAN-ADMINISTERED CLASS SATISFIES RULE 23

### A. Common Issues of Fact Predominate for the Physician-Administered Class

Defendants describe a number of hypothetical and largely unsupported factual scenarios in order to suggest that common issues of fact do not predominate with respect to Medicare Part B Class members. Defendants claim that reimbursement under Medicare Part B was subject to two different reimbursement regimes during the Class Period: (1) the lesser of 100% of AWP or estimated acquisition cost (from 1992-1997); and (2) the lesser of 95% of AWP or the actual charge (from 1998 to the filing of the MCC). However, because both "regimes" include reimbursement at levels directly tied to AWP, the existence of those regimes does not change the fact that common issues – namely, whether payment was based on AWP – predominate.

Defendants also suggest that purported individual issues with regard to how Medicare Part B reimbursement occurs preclude certification. First, Defendants claim that Carriers are

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<sup>48</sup> See App. 1(a) and App. 1(b); HRD at ¶¶ 46, 50, 55, 60. As Dr. Hartman explains, the Class' conduct in consistently pricing at AWP – 14% to 18% reveals their preferences and the information they were relying on, namely that such discounts were reasonable in relation to the spreads and does not indicate any knowledge of spreads of 50% to 300% on brand name drugs, or in the thousands on generic drugs.

<sup>49</sup> HRD at ¶¶ 3, 24(d), 44, pp. 3, 31, 57; see *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 206 (D. Mass. 2004); *Lupron*, 295 F. Supp. 2d at 175; *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 85 (D. Mass. 1998).



invested with discretion to administer Part B claims and that the exercise of that discretion results in variability in actual reimbursement. To support the existence of this so-called “discretion,” Defendants rely solely on Young, who provides no factual support for that opinion.<sup>50</sup> Moreover, even if Carriers had the discretion hypothesized by Young, the exercise of discretion does not preclude class certification as long as payment under Medicare Part B was tied to AWP.<sup>51</sup>

Second, Defendants claim that, because physicians *allegedly* sometimes charge less than the allowed amount, a jury would have to hear from thousands of physicians to determine whether reimbursement actually occurred at AWP. Defendants again rely on the factually unsupported declaration of Young for this proposition.<sup>52</sup> In so doing, Defendants misrepresent the deposition testimony of Plaintiffs’ expert Dr. Hartman. Dr. Hartman did not testify that he would have to interview thousands of physicians to demonstrate injury and damages. Instead, he testified that he would look at readily available reimbursement data for those physicians, as he has proposed doing throughout his Declaration.<sup>53</sup> Dr. Hartman has done so and it supports the uniform nature of use of AWP.<sup>54</sup> Further, an analysis of the only physician-administered contracts that Young cites in his declaration reveals that *all* reimburse physicians based upon AWP.<sup>55</sup>

Defendants further claim that Class members’ purported “understanding” that some portion of their payment would reimburse physicians for their fees, overhead, and other expenses in administering drugs would preclude certification. According to Defendants, in these circumstances, the jury would have to analyze Class members’ precise reimbursement for

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<sup>50</sup> See Young Decl., ¶¶ 169-72 (citing nothing factual, *i.e.*, reports or documents for the basis for his assertions). At best this opinion is raw speculation that is not admissible under any standard.

<sup>51</sup> See *In re Universal Serv. Fund Tel. Billing Practices Litig.*, 219 F.R.D. 661, 675 (D. Kan. 2004) (“Courts have recognized that the mere fact that defendants entered into price negotiations with their customers using the conspiratorially set price as a factor in the negotiations provides adequate proof of impact.”) (citing cases).

<sup>52</sup> See *id.* ¶ 170.

<sup>53</sup> See BRD Ex. 7 (Hartman Dep. at 274-77).

<sup>54</sup> HRD at ¶ 33(c), p. 46. Dr. Hartman analyzed data from ten payers and found an “obvious demonstrable relationship” between reimbursement and AWP.” See also HRD Attachment D1.

<sup>55</sup> HRD at ¶ 33(c), p. 46; App. 1(k).



services that were “bundled” with the product. However, the “understanding” to which Defendants refer does not exist.<sup>56/57</sup> Indeed, as Judge Stearns has suggested in similar AWP litigation regarding the drug Lupron, that Congress would set up a reimbursement scheme designed to allow physicians to profit in this matter is nonsensical. *See In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d at 163 (“The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual.”).

Finally, Defendants claim that the Medicare Part B Class cannot be certified because most Medicare beneficiaries purportedly have some form of insurance for their Medicare co-payment and that whether a Class member has such insurance will vary over time. Even if a Class member had insurance for part of the Class Period but not for another part of the Class Period, that would be an issue of damage allocation, not for class certification.<sup>58</sup> And if a beneficiary has insurance, that insurance company has a claim for damages and is a member of the Class. Insurance issues are thus a complete red herring on the Part B Class.

#### **B. Common Issues of Law Predominate**

Defendants argue that Plaintiffs cannot obtain certification under the applicable consumer protection statutes or the laws of civil conspiracy because those laws vary significantly. As demonstrated in Section VI, *infra*, this is not the case.

#### **C. The Named Plaintiffs Can Represent Medicare Part B Payers**

Finally, Defendants claim that the Medicare Part B Class should not be certified because the named Plaintiffs cannot represent Medicare Part B payers. They first claim that unique defenses will “skew the focus of the litigation.” However, courts in this District have

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<sup>56</sup> *See, e.g.*, BRD Ex. 8 (Beardstadt (John Deere) Dep. at 81) (“we didn’t want the use of injectable drugs to be a profit center.... We want to cover the reasonable cost of providing care, but we don’t look for those things to be a profit center.”); BRD Ex. 9 (Romasko (BCBS MT) Dep. at 70) (“We’d ideally like to pay what the pharmaceutical cost. To me it doesn’t make sense to make a profit on the drug itself, but on the service rendered.”)

<sup>57</sup> Defendants cannot identify any pre-litigation documents or evidence supporting the notion that AWP’s were inflated as a result of a desire to pay physician’s costs of administration.

<sup>58</sup> *See In re Cipro Cases I & II*, 121 Cal. App. 4th 402, 414 (4th Dist. 2004) (“It is settled that ‘a class action is not inappropriate simply because each member of the class may at some point be required to make an individual showing as to his or her eligibility for recovery or to the amount of his or her damages.’”) (citation omitted).

consistently refused to deny class certification where the named plaintiffs may have been subject to unique defenses such as lack of reliance, statute of limitations, or compulsory counterclaims.<sup>59</sup> The existence of those defenses would only counsel against class certification if they became “a major focus of the litigation.” *In re Synthroid Mktg. Litig.*, 188 F.R.D. at 291 (citations omitted). Defendants have made no such claim.

Second, Defendants claim that, although the Association Plaintiffs have submitted affidavits stating that their members did make co-payments under Medicare Part B, the “evidence suggests” that they did not. The only “evidence” that Defendants cite for this proposition is the deposition of Lauren Townsend, the Executive Director of CCJ, whom Defendants claim testified that “she could not state definitively whether any of CCJ’s members had, in fact, made a co-payment under Medicare B.” Defs.’ Combined Opp. at 41. With 1500 members, Ms. Townsend had a good faith basis for asserting that some Class members purchased Part B drugs. However, each of the Association Plaintiffs filed affidavits attesting to their motivation to end and remedy abusive AWP practices, the exact same motivation of any Part B Class members. Association Plaintiff CANY has 6,000 members and has asserted by affidavit that its members have made Part B co-pays. Defendants did not challenge its adequacy as a plaintiff.<sup>60/61</sup>

Finally, Defendants claim that the health and welfare funds are not typical of the absent Part B Class members they represent because, with the exception of UFCW, they do not allege that they made co-payments under Medicare Part B. Defendants therefore attempt to challenge UFCW’s claim that it did make co-payments by alleging that UFCW’s payments were

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<sup>59</sup> See, e.g., *Margaret Hall Found. v. Atlantic Fin. Mgmt.*, 1987 U.S. Dist. Lexis 7528, at \*7 (D. Mass. July 30, 1987); Opening Br. at 21 n.58. See also *Smilow*, 323 F.3d at 39.

<sup>60</sup> Affidavit of Citizen Action New York at ¶¶ 2-4.

<sup>61</sup> Defendants also claim that the Association Plaintiffs cannot adequately represent Class members asserting damage claims. For this proposition, Defendants rely on *Rosmer v. Pfizer, Inc.*, 2001 U.S. Dist Lexis 6678 (D.S.C. Mar. 30, 2001). However, that case merely held that a plaintiff in a products liability case who had already sustained his injuries could not represent a class of plaintiffs who sought medical monitoring – relief that would do nothing for the proposed class representative. *Id.*, at \*16. The Court said nothing about the broader proposition for which Defendants cite that case. Indeed, such reasoning does not apply here. It is well settled that “factual differences in the ... size or manner of purchase ... and other such concerns will not defeat class action certification when plaintiffs allege that the same unlawful course of conduct affected all members of the proposed class.” *In re Sumitomo Copper Litig.*, 182 F.R.D. 85, 92 (S.D.N.Y. 1998) (citations omitted).

“secondary” to Medicare, were allegedly rare, and were not related to the co-pay paid by the UFCW member. On the contrary, when Mr. Ryan testified that UFCW paid “secondary” to Medicare, he stated that UFCW paid the portion that Medicare did not, which is consistent with Plaintiffs’ proposed Class definition, and perfectly aligns UFCW as a proper Part B Class representative.<sup>62</sup> Moreover, since filing the opening brief on class certification Class members who paid for many Part B drugs have volunteered to act as Class plaintiffs thereby eliminating Defendants’ argument that UFCW is the only Part B payer.<sup>63</sup>

# **VI. COMMON QUESTIONS OF LAW PREDOMINATE OVER INDIVIDUAL QUESTIONS IN CONNECTION WITH PLAINTIFFS’ STATE LAW CLAIMS**

Defendants argue that the state claims asserted by the Part B and Third-Party Payer Class do not present common issues of law. Defendants are wrong.

## **A. Each Defendant’s Home State Consumer Protection Law Applies to All Class Members Under Massachusetts’ Choice of Law Rules**

### **1. The functional analysis approach favors application of the law of each Defendant’s home state**

Defendants do not deny that Massachusetts’ choice of law rules apply, yet Defendants ignore the Massachusetts Supreme Court’s “functional choice of law approach” set forth in *Bushkin Assocs., Inc. v. Raytheon Co.*, 393 Mass. 622, 631 (1985), and *Cosme v. Whitin Mach. Works*, 417 Mass. 643, 647 (1994). That approach considers, among other things, various RESTATEMENT (SECOND) OF CONFLICT OF LAWS (the “RESTATEMENT”) sections in order to determine whose law bears the “most significant relationship” to the claims and issues presented. RESTATEMENT sections 6 and 145 favor applying the law of each of defendant’s home states to the class claims, because, *inter alia*, those are the states where defendants hatched and implemented the alleged wrongdoing, and each of those states has an interest in regulating the

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<sup>62</sup> BRD Ex. 11 (Ryan Dep. at 86-87). In addition, Mr. Ryan in a declaration submitted with this reply describes how in fact UFCW has paid for its members Part B drugs.

<sup>63</sup> See Declaration of Glenn Randle of the Sheet Metal Workers National Health Fund and John Johnson of the Pirelli Armstrong Tire Corporation Medical Benefits Trust (“Johnson Decl.”). Plaintiffs hereby offer each as additional class representatives. Each fund has made co-pays under Part B, including for drugs manufactured by each Track 1 Defendant. Johnson Decl., ¶ 4.

conduct of resident defendants whose actions affect others both within and outside the state. *See* Opening Br. at 38-41.

Defendants utterly ignore RESTATEMENT §§ 6 and 145 and choose to rely *solely* on § 148, which only applies to the torts of fraud and misrepresentation – neither of which is at issue here. Moreover, § 148 does not trump the more general and overriding principles embodied in §§ 6 and 145.<sup>64</sup> It follows, then, that Defendants cases that rely on § 148 are also inapposite.<sup>65</sup>

Defendants also rely heavily on *In re Relafen Antitrust Litig.*, 221 F.R.D. 278 (D. Mass. 2004) (*see* Defs. Br. at 38; GSK Br. at 3), yet – with all due respect to Judge Young – the court erred by misapplying *In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 288 F.3d 1012 (7th Cir. 2002), and otherwise failing to give due consideration to all of the § 6 factors. *Relafen*, 221 F.R.D. at 276-77. *Bridgestone* applied Indiana choice of law rules, but Indiana is one of the last remaining states that still focus on the place where the harm occurred. Massachusetts has explicitly rejected this rule – known as *lex loci delicti* – as being too strict and rigid in application and now uses the “functional analysis” advocated by Plaintiffs in its place. *See Bushkin Assocs., Inc. v. Raytheon Co.*, 393 Mass. at 631-32. Other cases cited by Defendants recognize this. *See Tidemark*, 1993 U.S. Dist. Lexis 15307, at \*8; *Computer Sys.*, 571 F. Supp. at 1368. Unfortunately, the *Relafen* court relied heavily, and errantly, upon *Bridgestone* without noticing this crucial distinction – *lex loci* v. the Massachusetts approach – in its choice of law analysis.

The *Relafen* court did mention the “functional choice of law approach,” but only fleetingly, 221 F.R.D. at 277-78, and ignored other cases from this District in which the Court

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<sup>64</sup> Even if it did apply, the comments to § 148(2) make clear that § 6 – relied upon by Plaintiffs – takes precedence: the relative importance of contacts enumerated in § 148(2) “should be determined in the light of the choice-of-law principles stated in § 6 with emphasis upon the purpose sought to be achieved by the relevant tort rules of the potentially interested states, the particular issue and the tort involved.” *See* Comment *e*. This is only logical because § 6, appearing in the Introductory chapter of the RESTATEMENT and titled “Choice-of-Law Principles,” provides the overriding principles that govern all succeeding sections. Similarly, § 145 sets forth “The General Principle” that applies to all wrongs organized in Chapter 7 of the RESTATEMENT.

<sup>65</sup> *See Tidemark Bank for Sav., F.S.B. v. Morris*, 1993 U.S. Dist. Lexis 15307 (D. Mass. 1993); *Computer Sys. Eng'g Inc. v. Quantel Corp.*, 571 F. Supp. 1365, 1369-70 (D. Mass. 1983); Defs. Br. at 38; GSK Br. at 38 n.50. *Tidemark* is even further afield because the focus of the dispute in that case was on land, and § 148 places particular importance on applying the law of the forum in which land is found. 1993 U.S. Dist. Lexis 15307, at \*13; RESTATEMENT Comment *i*. Of course, land is not at issue here.

applied the law of a defendant's home state where the misconduct emanated from that state. *See Grace v. Perception Tech. Corp.*, 128 F.R.D. 165, 171 (D. Mass. 1989); *Randle v. SpecTran*, 129 F.R.D. 386, 393 (D. Mass. 1988). Plaintiffs respectfully submit that the court in *Relafen* should have placed a greater focus on each home state's interest in regulating the conduct of resident defendants whose actions affect consumers nationwide.

Furthermore, and contrary to Defendants' claim, the approach that Plaintiffs suggest here is far from novel. Many courts choose to apply the substantive law of the defendant's headquarters or principal place of business to a nationwide class despite variances in state law, as Judge Keeton observed in certifying pendent state law claims on behalf of a nationwide class. *See Randle*, 129 F.R.D. at 393. Judge Keeton's rationale applies with equal force here.<sup>66/67</sup>

In the present litigation, it is proper to apply Defendants' home state laws where those states are the principal places of business and the conduct at issue emanated from those states.

## **2. There is no constitutional impediment to applying Defendants' home state laws**

Defendants incorrectly claim that Plaintiffs' choice of law analysis will "raise serious constitutional issues" (*see* Defs. Br. at 38; GSK Br. at 7-10). Defendants misapply the seminal authority in this arena, *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 806-814 (1985), but misapply it. *Shutts* held that a state must have a "significant contact or significant aggregation of contacts" to apply its laws to "claims asserted by each member of the plaintiff class." *Id.* at 821. In contrast to the facts in *Shutts*, in the present litigation each one of Defendants' home states *has* a "significant contact" with the Plaintiffs' claims by virtue of Defendants' locations there and the

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<sup>66</sup> Defendants attempt to write-off *Randle* by proclaiming that Judge Keeton engaged in only a "cursory analysis," yet the court applied *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985) (discussed *infra*), and carefully evaluated the factors that favored the application of Massachusetts law.

<sup>67</sup> *See also In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 252 (D. Del. 2002) ("Where the defendant's headquarters are located in Delaware and the alleged deceptive acts originated in Delaware, it is proper to apply the Delaware consumer fraud statute to a nationwide class."), *aff'd*, 2004 U.S. Dist. Lexis 25180 (3d Cir. Dec. 8, 2004); *Grace v. Perception Tech. Corp.*, 128 F.R.D. at 171 (application of Massachusetts law proper because defendants were headquartered in Massachusetts, and the alleged misrepresentations emanated from Massachusetts); *In re Bendectin Litig.*, 857 F.2d 290, 303-05 (6th Cir. 1988) (applying Ohio law to plaintiffs nationwide based on the location of defendant's principal place of business); *In re Lutheran Bhd. Variable Ins. Prods. Co. Sales Practices Litig.*, 2004 U.S. Dist. Lexis 7789, at \*15-16 (D. Minn. Apr. 28, 2004) (certifying nationwide class under Minnesota Consumer Fraud Act where defendant was headquartered in Minnesota, and misrepresentations at issue were made from those headquarters).

fact that each home state is the center of gravity for the pricing and marketing decisions for the drugs at issue. Therefore, there is nothing unfair or arbitrary about applying a Defendant's home state law against it.

Importantly, *Shutts* is the one and only applicable test for constitutional choice of law analysis in Supreme Court jurisprudence. See, e.g., *Franchise Tax Bd. v. Hyatt*, 538 U.S. 488, 494 (2003) (“For a State’s substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair.”) (quoting *Shutts*); *Campbell*, 538 U.S. at 421-22 (citing *Shutts*); *Randle*, 129 F.R.D. at 393 (quoting *Shutts*); *In re Cordis Corp. Pacemaker Liab. Litig.*, 1992 U.S. Dist. Lexis 22612, at \*50 (S.D. Ohio Dec. 23, 1992) (citing *Shutts*). Therefore, Defendants’ so-called due process arguments have no bearing because *Shutts*’ “significant contact” test is satisfied here.<sup>68</sup>

Finally, courts have not been troubled by constitutional concerns in applying one state’s consumer protection statute to the benefit of out-of-state consumers and against a defendant headquartered within the state.<sup>69</sup>

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<sup>68</sup> Hence, Defendants’ citations to *Healy v. Beer Inst.*, 491 U.S. 324 (1989), and *Younger v. Harris*, 401 U.S. 37, 44 (1971), are unavailing. *Healy* involved interferences with interstate commerce inasmuch as it regulated activity occurring *wholly* outside the boundary of the state, 491 U.S. at 337, and *Younger* addressed a drastic situation in which “federal courts are asked to enjoin pending proceedings in state courts.” 401 U.S. at 45. These cases have no bearing here for two reasons. First, and most importantly, neither case involved a *Shutts* analysis. Second, the instant case does not engender the type of conflicts with interstate commerce implicated in *Healy* and *Younger* because, as discussed in Plaintiffs’ opening brief and again *infra*, all 50 states and the District of Columbia have enacted consumer protection statutes, most of which are patterned after the FTC Act. Thus, it cannot rationally be argued that applying a Defendant’s home state consumer statute here will result in a *policy interest* in direct conflict with those of other states with similar statutes – let alone a conflict of such proportion as to invoke Commerce Clause or Federalism concerns. Defendants’ reliance on *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003), is also misplaced. The due process concern at issue in *Campbell* was the assessment of punitive damages by the jury based on conduct that did not relate to the plaintiffs and claims before the court but included conduct in other states where such conduct was not unlawful. *Id.* at 421-22. This issue is not implicated here, where Plaintiffs allege that Defendants’ conduct was unlawful everywhere. For this same reason, Defendants’ reliance on *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996), is unfounded. See *id.* at 572 (one state sought to subject another state’s tortfeasor to punitive damages that were not imposed in that other state).

<sup>69</sup> See, e.g., *In re Lutheran Bhd.*, 2004 U.S. Dist. Lexis 7789, at \*15 (“There is no constitutional impediment to applying the Minnesota CFA to the claims of non-resident class members.”); *Warfarin Sodium Antitrust Litig.*, 212 F.R.D. at 248 n.15 (citing *Shutts*); *Grace*, 128 F.R.D. at 171 (citing *Shutts*); *Randle*, 129 F.R.D. at 393 (citing *Shutts*).

**B. Common Questions of Law Predominate Even If the Court Wishes to Apply Multi-State Law**

**1. Defendants have not established that state law variations are significant and material to the particular matters in dispute and are otherwise unmanageable**

**a. Plaintiffs have demonstrated that relevant state law variations – while few – can be efficiently managed**

Significant differences in state law do not preclude certification, and it is important for courts to distinguish between variations that “are pertinent to the issues being certified and those which are unimportant to these questions.” *In re Teletronics Pacing Sys., Inc.*, 172 F.R.D. 271, 292 (S.D. Ohio 1997).<sup>70</sup> To deny certification, the variations must be (i) significant and material to the issues contested in the case and (ii) cannot otherwise be addressed efficiently through the creation of subclasses or the use of jury instructions and special verdict forms. *Id.*; see also *In re Prudential Ins. Co. of Am. Sales Practice Litig.*, 962 F. Supp. 450, 525 (D.N.J. 1997).

Plaintiffs explained that the elements of the tort of civil conspiracy are nearly identical in each state and, where nuances exist (for instance, with respect to whether a defendant must have intended to cause injury), they are not material, thus ensuring that common issues of law predominate for Plaintiffs’ civil conspiracy claims. See Opening Br. at 42 & Appendix A. With respect to the consumer protection claims, Plaintiffs recognized that a few material variations exist and have, consequently, followed well-established jurisprudence and proposed subclasses to account for those few states that have differing scienter and reliance requirements. See Opening Br. at 45. Thus, Plaintiffs have demonstrated that the state law claims can be efficiently managed and that state law variations do not “swamp” common issues. See *Mowbray v. Waste Mgmt. Holdings, Inc.*, 189 F.R.D. 194, 199 (D. Mass. 1999).

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<sup>70</sup> The Sixth Circuit ultimately reversed certification of a no-opt-out settlement class on the basis of constitutional considerations. See *In re Teletronics Pacing Sys.*, 221 F.3d 870 (6th Cir. 2000). The court, however, left intact Judge Spiegel’s rationale supporting nationwide certification. See also *Simon v. Philip Morris*, 124 F. Supp. 2d 46, 77 (E.D.N.Y. 2000) (use of subclasses to accommodate variations in state law “is fair and routine”) (citing cases); *In re Prudential Ins. Co. Am. Sales Practices Litig. Agent Actions*, 148 F.3d 283, 315 (3d Cir. 1998) (“Courts have expressed a willingness to certify nationwide classes on the ground that relatively minor differences in state law could be overcome at trial by grouping similar state laws together and applying them as a unit.”).



**b. Defendants do not cite to any significant and material state law variations that serve to swamp commonality**

Defendants cite to a litany of purported state law differences yet not one of them defeats certification. Barely mentioning Plaintiffs' civil conspiracy claims (*see* Defs. Br. at 37 n.47; GSK Br. at 1), Defendants fail to distinguish material elements in any one state's civil conspiracy law from another state's and otherwise fail to demonstrate that civil conspiracy laws differ in any substantial manner from state-to-state. Indeed, Defendants' survey of conspiracy law contained in their Appendix B only confirms the substantial similarity of the elements. For instance, Defendants make no attempt to distinguish the salient elements listed in Plaintiffs' civil conspiracy table or the cases from which they are derived. In addition, Defendants list variations on the burden of proof (Defs. Br. at App. B), but they do not allege that Plaintiffs fail to meet any of those standards. Furthermore, Defendants reference slight variations on proximate cause but do not allege that Plaintiffs fail to meet the proximate cause standard in any one of these states; indeed, Dr. Hartman's "but for" analysis satisfies the causation element in every state. Thus, Defendants have failed to demonstrate that any purported variations in civil conspiracy law are significant and relevant here for purposes of managing this case.

Defendants fare no better with respect to the state consumer protection claims. Defendants note differences between statutes that broadly prohibit unfair or deceptive practices and those that prohibit a list of specific practices, *see* GSK Br. at 4, yet fail to challenge Plaintiffs' assertion that the allegations of the AMCC establish violations of *both* types of statutes. In other words, Defendants cannot deny that Plaintiffs' allegations, if established, will violate both types of statutes. Defendants also cite to variations in requirements for reliance and scienter, GSK Br. at 4-5, yet Plaintiffs have proposed subclasses to account for such differences, and Defendants do not explain why those subclasses cannot be used to efficiently manage the claims. Indeed, these carve-outs – which affect Class members in only 12 states – “do[] not outweigh the multitude of issues common to the remaining elements and claims.” *In re*



*Prudential*, 962 F. Supp. at 516.<sup>71</sup> And, Defendants speculate that causation standards may vary from state to state, but again fail to point out any material differences. *See* GSK Br. at 5-6.<sup>72</sup>

Finally, Plaintiffs explained that proving the elements of RICO will satisfy the elements of consumer protection act claims nationwide, as Judge Stearns recognized in *Lupron*. *See* Opening Br. at 42-43 (citing 295 F. Supp. 2d at 181). Defendants had no response to this observation.

**c. Defendants' cases are inapposite**

Defendants' principal authorities are distinguishable because they involved *defective products* that invoke subsidiary concepts of duty of care, foreseeability, and very complex medical/scientific causation issues, which lead to legal inquiries that can vary substantially from state to state.<sup>73</sup> In contrast, the instant case is a consumer fraud, market-wide *pricing* action involving standardized conduct by Defendants and not the variety of individual fact and legal

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<sup>71</sup> *Scienter* does not present any individualized issues, because the AMCC alleges that Defendants acted with intent to defraud. Furthermore, common issues still predominate in the reliance subclass because courts have recognized that direct evidence of reliance is not required, or reliance is otherwise presumed where there are common omissions across an entire class. *See, e.g., Chisolm v. TranSouth Fin. Corp.*, 194 F.R.D. at 560; *In re Prudential*, 962 F. Supp. at 516; *In re Synthroid Mktg. Litig.*, 188 F.R.D. 295, 300 (N.D. Ill. 1999); *Cope v. Metropolitan Life Ins. Co.*, 696 N.E.2d 1001, 1008 (Ohio 1998); *Rohlfing v. Manor Care*, 172 F.R.D. 330, 338 (N.D. Ill. 1997) (citing cases).

<sup>72</sup> Furthermore, whatever the label applied to the causation inquiry, each state requires legal causation, and Dr. Hartman's "but for" model will satisfy the causation standard in any state, whether the standard is "but for" or the weaker "substantial factor" test. *See, e.g., Teletronics*, 172 F.R.D. at 292-93 (noting that causation under tort law is essentially the same inquiry in each state, whether it is labeled "proximate" or "legal" causation); *Bendectin*, 857 F.2d at 311 (finding that pleadings meeting the stricter "but for" causation standard will, by definition, fulfill the weaker substantial factor test). Defendants also complain that damage determinations *may* vary from statute to statute, GSK Br. at 6, but Defendants fail to explain how. In any event, varying state law damage remedies are "rarely determinative under Rule 23(b)(3)," *Smilow*, 323 F.3d at 40, and are considered in the context of calculating damages. *In re Warfarin Sodium Antitrust Litig.*, 2004 U.S. App. Lexis 25180, at \*30 (3d Cir. Dec. 8, 2004).

<sup>73</sup> *See* GSK Br. at 1 n.2 and 6 n.30, citing: *Bridgestone*, 288 F.3d at 1019 (too many questions surrounding whether and why tires failed made case unmanageable); *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1186 (9th Cir.) (defective pacemakers, noting that "[o]ur circuit has recognized the potential difficulties of 'commonality' and 'management' inherent in certifying products liability class actions.") (citing cases), *amended*, 273 F.3d 1266 (9th Cir. 2001); *Castano v. American Tobacco Co.*, 84 F.3d 734, 743 (5th Cir. 1996) (novel nicotine addiction-as-injury case); *In re Am. Med. Sys.*, 75 F.3d 1069, 1085-86 (6th Cir. 1996) (defective penile prostheses); *Lewis Tree Serv. v. Lucent Techs., Inc.*, 211 F.R.D. 228 (S.D.N.Y. 2002) ("Y2K" defect in telecommunications equipment); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002) (drug allegedly caused liver and heart ailments); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133 (E.D. La. 2002) (drug allegedly caused dangerous heartbeat irregularities); *Block v. Abbott Labs.*, 2002 U.S. Dist. Lexis 5453 (N.D. Ill. Mar. 28, 2002) (defective lab test that produced results showing false positives for cancer); *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 194 F.R.D. 484 (D.N.J. 2000) (defective ignition switches); *Lyon v. Caterpillar, Inc.*, 194 F.R.D. 206 (E.D. Pa. 2000) (defective boat engines); *Kaczmarek v. IBM*, 186 F.R.D. 307 (S.D.N.Y. 1999) (defective computers); *Chin v. Chrysler Corp.*, 182 F.R.D. 448 (D.N.J. 1998) (defective brake system); *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332 (D.N.J. 1997) (defective ignition switches).

issues associated with products liability actions. Consequently, Defendants' cases are not persuasive.

## 2. Courts frequently certify multi-state claims

In Defendants' fictional world, no court could ever certify a class action applying multi-state law. But as pointed out in Plaintiffs' opening brief, many courts have certified nationwide classes under the laws of the various states, including actions alleging overpayment for prescription drugs and even some product defect actions.<sup>74</sup> Many of the certifications involved tort causes of action that can have a higher degree of variation from state-to-state than the relatively more uniform consumer protection acts.<sup>75</sup> Defendants fail to even mention – let alone attempt to distinguish – these authorities.

## VII. A CLASS ACTION IS A SUPERIOR METHOD FOR ADJUDICATION OF PLAINTIFFS' CLAIMS

In asserting that this litigation is unmanageable as a class action, Defendants totally ignore Plaintiffs' supporting authorities – failing to respond to any of the cases relied on by Plaintiffs – and instead rely on a litany of inapposite personal injury and other mass tort cases. But because liability, causation and damages here can be proved with common evidence, making a class action superior to countless individual actions,<sup>76</sup> the recent consumer and commercial class actions that Plaintiffs cite serve as paradigms for the Court to follow.<sup>77</sup> Defendants'

<sup>74</sup> See, e.g., *In re Warfarin Sodium Antitrust Litig.*, 2004 U.S. App. Lexis 25180, at \*29 (“variations in the rights and remedies available to injured class members under the various laws of the fifty states ... does not defeat commonality and predominance”); *In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 369 (D.D.C. 2002) (certifying settlement class under various state antitrust laws); see also *Hanlon v. Chrysler Corp.*, 150 F.3d 1011 (9th Cir. 1998); *Shaw v. Toshiba Am. Info. Sys.*, 91 F. Supp. 2d 942, 956-57 (E.D. Tex. 2000); *Deadwyler v. Volkswagen of Am., Inc.*, 1986 U.S. Dist. Lexis 28449 (W.D.N.C. 1986).

<sup>75</sup> See, e.g., *Teletronics*, 172 F.R.D. 271 (product liability); *In re Copley Pharm., Inc.*, 161 F.R.D. 456, 465 (D. Wyo. 1995) (defective products case certified under product liability laws); *In re Prudential Ins. Co. Am. Sales Practice Litig.*, 148 F.3d 283 (3d Cir. 1998) (common law fraud, breach of contract, bad faith, negligent misrepresentation, negligence, unjust enrichment, in addition to breach of state consumer fraud statutes; affirming nationwide certification of class under multi-state law where plaintiffs compiled a series of charts setting forth comprehensive analyses of various state laws demonstrating that the elements of the claims were substantially similar with differences falling into a limited number of predicable patterns); *In re School Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986) (affirming nationwide certification under multi-state product liability laws where plaintiffs grouped claims into four categories).

<sup>76</sup> Of course, many of the putative Class members would not be able to pursue individual cases given the huge financial burden of litigating against such well-heeled Defendants.

<sup>77</sup> Plaintiffs' principal cases, cited in Plaintiffs' opening brief and Trial Plan and discussed again below, are: *Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004); *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656 (7th Cir. 2004); *In re Terazosin Hydrochloride Antitrust Litig.*, 203 F.R.D. 551, 559 (S.D. Fla. 2001); *In re Visa*

misinterpretation of Plaintiffs' Trial Plan and invocation of inapposite tort cases highlights the fact that Defendants have no supporting authority or logic with which to validly attack Plaintiffs' cogent Trial Plan.

**A. Plaintiffs' Cogent, Two-Phase Trial Plan Is Well Grounded in Fact and Law and Supported by Extensive Case Authority**

As detailed in Plaintiffs' opening brief, under Plaintiffs' Trial Plan, the jury will make classic causation findings in Phase I based on, among other things, documents and testimony from Defendants showing that the injury to Class members in the form of higher drug prices was a foreseeable and intended consequence of Defendants' AWP inflation; expert testimony regarding the ubiquity of AWP as a reimbursement benchmark; examples of private payer contracts utilizing AWP as a benchmark; and expert testimony demonstrating that Defendants inflated AWP, which formed the basis for the reimbursements made by Plaintiffs and the Class (the fact of damage). In Phase I, Dr. Hartman will also assess the amount of aggregate class damage, or alternatively assess the amount of the illegal spread on a per drug basis, thereby allowing for proof in Phase II of AWP-based purchases and the prices paid over the legal maximum set by the jury in Phase I. *See* Trial Plan, Phase I.

Phase II will then focus on evaluating individual Class member damage claims. A Special Master will be charged with determining each individual Class member's damage based on proofs of claim and claims data showing AWP-based reimbursement provided by the Class members and rebuttals, if any, offered by Defendants. The Special Master evaluates each damage claim pursuant to a formulaic calculation provided by Plaintiffs' expert that will have been approved by the Phase I jury. *See* Trial Plan, Phase II.

Trying a class action in this manner is not novel. To the contrary, and as demonstrated below, it is a rather common method of adjudicating complex class claims.

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*Check/MasterMoney Antitrust Litig.*, 280 F.3d 124 (2d Cir. 2001); and *Chisolm v. TranSouth Fin. Corp.*, 194 F.R.D. 538, 563 (E.D. Va. 2000). Plaintiffs also draw the Court's particular attention to, *In re IPO*, 2004 U.S. Dist. Lexis 20497 (S.D.N.Y. Oct. 13, 2004), which was decided after Plaintiffs' filed their motion.

**1. Bifurcation is a tool commonly used in complex, commercial class action litigation and is particularly appropriate here given the substantial magnitude of common issues**

Many courts have adopted a two-phase approach to trial – similar to that advanced by Plaintiffs here – in which common issues are tried on a class-wide basis in Phase I followed by separate treatment for individual issues, which is logical given Rule 23(e)(4)’s command that “[w]hen appropriate ... an action may be brought or maintained as a class action with respect to particular issues....”<sup>78</sup> Indeed, it is common to hold separate proceedings to determine whether individual Class members are entitled to relief in a remedy phase after liability on a common basis has been found. For instance, in *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124 (2d Cir. 2001), the court described many of the management tools available to a district court to address individualized damages issues: (i) bifurcating liability and damage trials with the same or different juries; (ii) appointing a magistrate judge or special master to preside over individual damages proceedings; (iii) decertifying the class after the liability trial and providing notice to Class members concerning how they may proceed to prove damages; (iv) creating subclasses; or (v) altering or amending the class. *Id.* at 141.<sup>79</sup> In *Visa Check*, the district court certified the claims, satisfied that the plaintiffs’ expert could establish injury in fact on a class-wide basis using common proof, notwithstanding the presence of individualized damages questions. 192 F.R.D. at 86. Even wide disparity among class members as to the amount of damages suffered does not necessarily mean that class certification is inappropriate, and courts have certified classes in light of the need for individualized calculations of damages in follow-on proceedings.<sup>80</sup>

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<sup>78</sup> Rule 23(e)(4) also provides that “a class may be divided into subclasses and each subclass treated as a class, and the provisions of this rule shall then be construed and applied accordingly.”

<sup>79</sup> See also *Klay v. Humana, Inc.*, 382 F.3d at 1273 (quoting *Visa*); *Carnegie v. Household Int’l, Inc.*, 376 F.3d at 661 (quoting *Visa*); *Robinson v. Metro-North Commuter R.R.*, 267 F.3d 147, 168 (2d Cir. 2001) (“[L]itigating the pattern-or-practice liability phase for the class as a whole would both reduce the range of issues in dispute and promote judicial economy. ... [E]ven assuming that the remedial stage is ultimately resolved on a non-class basis, the issues and evidence relevant to these individual adjudications would be substantially narrowed.”).

<sup>80</sup> *Bell Atl. Corp. v. AT&T Corp.*, 339 F.3d 294, 306 (5th Cir. 2003) (refusing to reverse denial of class certification on basis that lost profit damages presented too many individual issues); *Carnegie*, 376 F.3d at 662 (courts will certify class actions when other issues, such as questions of reliance and individual damages, can be left for resolution in satellite proceedings); *Moore v. PaineWebber, Inc.*, 306 F.3d 1247, 1255-56 (2d Cir. 2002) (same). See also, e.g., *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 456 (3d Cir. 1977) (noting that “[i]f for any reason the

Defendants simply *ignore* these seminal authorities. Consistent with the above authorities, Phase I of Plaintiffs' Trial Plan presents a plethora of common issues triggered by *Defendants' conduct*, while reserving for Phase II for what is likely to be a largely proof-of-claim procedure.

## 2. Defendants' cases are inapposite

In attacking Plaintiffs' Trial Plan, Defendants cite a litany of mass tort cases, which are difficult to try as class actions because the diversity of symptoms and causation issues associated with personal injuries frequently trumps commonality among the varied class members. *See Castano v. American Tobacco Co.*, 84 F.3d at 746-47 & n.23 (observing that certification of mass tort litigation classes has been disfavored) (collecting cases). *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990), relied upon heavily by Defendants, is the prototypical latent injury case that frequently defies certification. Consequently, expert testimony could not be used to determine disease causation on a class-wide basis, and common issues could not predominate without inappropriately "restat[ing] the dimensions of tort liability." *Id.* at 711-12. The instant case contrasts sharply with *Fibreboard* given Dr. Hartman's causation model and the fact that this is not a latent personal injury exposure case.<sup>81</sup>

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district court were to conclude that there would be problems involved in proving damages which would outweigh the advantages of class certification, it should give appropriate consideration to certification of a class limited to the determination of liability."); 7B CHARLES A. WRIGHT, ARTHUR R. MILLER & MARY K. KANE, FEDERAL PRACTICE AND PROCEDURE § 1781 (2d ed. 1986) ("The question of damages can be severed from that of liability and tried on an individual basis.").

<sup>81</sup> Defendants' other tort cases are similarly inapposite. *See In re Paxil Litig.*, 212 F.R.D 539, 548 (C.D. Cal. 2003) (myriad of individual issues served as an "overarching barrier" to class certification, including differing drug doses for different ailments, the potential presence of interactions with other drugs ingested by patients, and a wide variety of purported physical and mental symptoms); *In re American Med. Sys.*, 75 F.3d at 1084 (in "medical device products liability litigation of the sort involved here the factual and legal issues often *do* differ dramatically from individual to individual because there is no common cause of injury."); *Castano*, 84 F.3d at 743 & n.15, 749 ("injury-as-addiction" claim was novel and involved too many individualized inquiries because class members were exposed to nicotine through different products, for different amounts of time, and over different time periods; each class member's knowledge about the effects of smoking differs; and each plaintiff began smoking for different reasons); *Blyden v. Mancusi*, 186 F.3d 252 (2d Cir. 1999) (doubting wisdom of certification in section 1983 case involving a wide variety of individualized considerations stemming from alleged prison beatings following a riot). Notably, while the injury cases cited by Defendant generally fall on the difficult-to-certify end of the veritable class action continuum, some courts will certify mass tort class actions. *See, e.g., Hilao v. Estate of Marcos*, 103 F.3d 767 (9th Cir. 1996); *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 145, 164-65 (2d Cir. 1987) (cited by Defendants). Indeed, cases like *Cimino* do not stand for the proposition that group causation trials can never be done, only that it cannot be done under Texas law in asbestos injury cases.

Defendants' few commercial case cites are also inapposite. *Windham v. American Brands*, 565 F.2d 59 (4th Cir. 1977), does not apply because, unlike the uniform price benchmarking at issue here, the wide variety of geographical markets, daily price fluctuations and individualized systems for grading product quality prevented demonstration of common injury from an alleged conspiracy to control prices in tobacco auctions. *Id.* at 68-69; *see also Nichols v. Mobile Bd. of Realtors, Inc.*, 675 F.2d 671, 679 (5th Cir. 1982) (plaintiffs failed to present a viable theory of generalized proof for the fact of damage) (cited by Defendants).<sup>82</sup>

In stark contrast to all of Defendants' authorities, causation here does *not* turn on a plaintiff-by-plaintiff assessment and is based on common proof.<sup>83</sup> Furthermore, the Trial Plan does not contemplate extrapolating damage calculations from one group of plaintiffs to another, a critical defect that doomed the *Cimino* plan. To the contrary, Phase II calls for each Class member to prove individual damages, and preserves the ability of the jury to evaluate the recommendation that the Special Master will make on a Class member-by-Class member basis. Thus, none of Defendants' cases remotely approach the uniformity of issues that are germane to unfair *pricing* cases like that at issue here, which by their very nature have a more generalized and uniform impact on the marketplace, are particularly amenable to common liability and damages models presented by experts, and are therefore frequently certified as class actions.<sup>84</sup>

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<sup>82</sup> Defendants' other commercial cases also involved individual representations and, for that reason, are not persuasive. *See In re LifeUSA Holding*, 242 F.3d 136, 148 (3d Cir. 2001) (claims arose from individual misrepresentations, neither uniform nor scripted, made by some 30,000 independent agents to over 280,000 purchasers); *Zimmerman v. Bell*, 800 F.2d 386, 390 (4th Cir. 1986) (fraud itself was specifically revealed to the market and, in any event, the case predates fraud-on-the-market theory); *Simer v. Rios*, 661 F.2d 655, 673 (7th Cir. 1981) (individual issues of reliance and state of mind precluded certification, as did difficulty in identifying class members). Defendants' reliance on *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331 (4th Cir. 1998), is equally misplaced. The proposed class at issue there contained members with irreconcilable conflicts (a substantial percentage of class members had already released defendants in exchange for operating concessions), and the contracts at issue contained materially different language defining the legal obligations, casting doubt on whether defendants even breached the contracts of a significant percentage of the class members. These factors rendered plaintiffs' claims atypical, failed to present common questions of law and fact and therefore "seriously infected the class certification." *Id.* at 340. Furthermore, the tort claims were predicated "on the shifting evidentiary sands of individualized [oral] representations to franchisees," *id.* at 340-41, and, in any event, required a showing of reliance. *Id.* at 341. None of these disparate issues are remotely invoked in the instant case where all Class members were directly impacted by inflated AWP benchmarks.

<sup>83</sup> HRD at ¶ 3(d), p. 4, Section V.

<sup>84</sup> *See, e.g., Humana*, 382 F.3d at 1259-60 ("Plaintiffs need only come forward with plausible statistical or economic methodologies to demonstrate impact on a class-wide basis."); *Carnegie*, 376 F.3d at 663 (upholding certification in RICO case where "[t]he question whether RICO was violated can be separated from the question whether particular intended victims were injured"); *In re Terazosin Hydrochloride Antitrust Litig.*, 203 F.R.D. at 559 (upholding class certification where Dr. Hartman offered an "algebraic formula for the computation of class



Plaintiffs' Trial Plan does not suffer from the infirmities cited in Defendants' cases — cases that cannot trump the application of *Humana*, *Carnegie*, *Terazosin*, and *Visa Check* to Plaintiffs' motion for class certification.<sup>85</sup>

### 3. The trial plan does not abrogate Defendants' due process rights

Defendants assert that Plaintiffs' Trial Plan abrogates Defendants' constitutional right to have a single jury decide related facts and issues and otherwise violates Defendants' rights to a fair trial. Defs. Br. at 45-46. In making this argument, Defendants fail to identify the specific, identical issues that two separate juries would be called upon to decide, which alone necessitates rejection of Defendants' argument. *See Mowbray*, 208 F.3d at 492.<sup>86</sup> Furthermore, Defendants misconstrue Plaintiffs' Trial Plan, and a careful comparison of the cases relied upon by Defendants with Plaintiffs' actual Trial Plan resoundingly demonstrates that none of Defendants' concerns are valid.

Defendants cite *Alabama v. Blue Bird Body Co., Inc.*, 573 F.3d 309, 318 (5th Cir. 1978), and *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995), where the courts were concerned with bifurcation leading to the second jury's reconsideration of findings made by the first jury. The rationale: "if separate juries are allowed to pass on issues involving overlapping legal and factual questions the verdicts rendered by each jury could be inconsistent." *Blue Bird Body*, 573 F.3d at 318.<sup>87</sup> Thus, the court explained that Phase I must include evidence showing a causal link between the law violation and the alleged injury before Phase II may commence for

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members' overcharge damages" despite the fact that "the jury will also have to consider some individualized evidence in rendering individual damage calculations"; *Visa Check*, 280 F.3d at 139 (common issues predominate when liability can be found on a class-wide basis notwithstanding individualized damage issues).

<sup>85</sup> Recycling the same arguments made against the predominance of common issues, Defendants' insist that each and every Class member must be examined to determine "what each class member knew and when he, she or it knew it" (Defs. Br. at 46) and must make individualized causation showings (Defs. Br. at 44-45). As discussed above, Defendants totally misconstrue Plaintiffs' claims. Rather than rehash why here, Plaintiffs refer the Court to Sections III-IV, *supra*.

<sup>86</sup> Defendants only baldly claim that unspecified "interrelated issues of fraud, causation and other matters" would be considered by separate juries. Defs. Br. at 45.

<sup>87</sup> The plaintiffs in *Blue Bird Body* failed to present any expert testimony establishing common impact and merely cited excerpts from the deposition of one distributor. *Id.* at 321. In *Rhone-Poulenc*, a case brought by and on behalf of hemophiliacs infected by the AIDS virus, the Phase I jury would determine whether defendants were negligent but would not determine whether defendants were liable. Issues such as comparative negligence and proximate causation were reserved for follow-on litigation, and these issues overlapped the issue of defendants' negligence. 51 F.3d at 1303.

calculation of individual damages. *Id.* at 317. But, under Plaintiffs' Trial Plan here, Dr. Hartman's "but for analysis" will demonstrate, *inter alia*, class-wide impact in Phase I.<sup>88</sup> This impact will not be re-evaluated in Phase II, and there is no risk that the second jury will second-guess or otherwise overturn the findings made by the jury in Phase I – unlike the procedure at issue in *Blue Bird Body*.

Defendants next argue that individual issues cannot be litigated through the use of claim forms, random sampling, expert opinion and a Special Master without offending due process. Defs. Br. at 46. This again misconstrues Plaintiffs' Trial Plan. The only individual issues at stake – the amount of damages per Class member and possibly some affirmative defenses related thereto – will be litigated in individual proceedings, providing Defendants with the opportunity to challenge any claim forms and the veracity of the necessary documentary and data-based evidence. There will be no random sampling, and Defendants will maintain the right to challenge any findings made by the Special Master. *See Chisolm*, 194 F.R.D. at 553 (approving of use of special master to take individual damages evidence in Phase Two and submit a report to the jury, which will be considered evidence along with other relevant evidence). Thus, the two mass tort cases that Defendants rely on simply do not apply here. *See Arch v. American Tobacco Co.*, 175 F.R.D. 469, 493 (E.D. Pa. 1997). *Fibreboard*, 893 F.2d at 710-12.<sup>89</sup>

#### **4. Affirmative defenses do not vitiate superiority**

Nor do affirmative defenses bar certification. The question of whether publicly available information should have put a particular class member on notice of the fraud *is itself a class-wide issue*. If "everyone knew" of the fraud – as Defendants have repeatedly inferred without proof throughout this litigation – then knowledge of the schemes may possibly be imputed to the entire class.<sup>90</sup> Moreover, Plaintiffs have made detailed allegations of fraudulent concealment,

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<sup>88</sup> HRD at Section V.

<sup>89</sup> Although Defendants cite *Fibreboard* in support of their due process argument, the court there did not rule on due process issues, finding only that common issues did not predominate. *See id.* at 712.

<sup>90</sup> *See In re IPO*, 2004 U.S. Dist. Lexis 20497, at \*98, \*148 (the question of whether publicly available information would have put a particular class member on notice of the fraud presents an important class-wide issue); *Chisolm*, 194 F.R.D. at 561 (whether reliance was reasonable is an objective inquiry common to the entire class).



which places the focuses on what *the defendants did* rather than what plaintiffs did (or did not do).<sup>91</sup>

Indeed, Defendants' sole authority in this arena – *Mowbray* – actually supports certification. Like Defendants do here, the defendant in *Mowbray* argued that separate statute of limitations determinations for individual plaintiffs and class members precluded class treatment. The court disagreed, holding that “[a]s long as a sufficient constellation of common issues binds Class members together, variations in the sources and application of statutes of limitations will not automatically foreclose class certification under Rule 23(b)(3).” 208 F.3d at 296. The court also observed that “a common proffer likely would establish the factual predicate necessary for a tolling determination.” *Id.* at 297. In this case, the critical concealment question is whether Defendants actively concealed their manipulation of AWP’s, which proof will be common among Class members. The question is not whether the Class members knew that they should have been paying less for the drugs, for “[i]t is the fact of concealment that is the polestar in an analysis of fraudulent concealment. It is the camouflage that demands attention, the cover up, the acts of obscuring or masking.” *Linerboard*, 305 F.3d at 163.

## **B. The Proposed Individual Damages Phase Is Manageable**

Defendants conjure up a speculative “parade of horrors” in asserting that the Phase II damages phase would be unmanageable. Defs. Br. at 47-48. To the contrary, Phase II, which focuses on calculating damages for each individual Class member, is nonetheless manageable and a superior manner of determining damages once class-wide liability is found in Phase I.

### **1. Damages are commonly calculated on an individual basis in Class litigation**

Individualized damage proceedings are common in class actions.<sup>92</sup> “The individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3),” and courts have

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<sup>91</sup> See *In re Vitamins Antitrust Litig.*, 209 F.R.D. 251, 269-70 (D.D.C. 2002) (common issues prevail over individual issues regarding fraudulent concealment); *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 162 (3d Cir. 2002) (common issues prevail over fraudulent concealment individual issues), *cert. denied*, 538 U.S. 977 (2003); *Weil v. Long Island Sav. Bank, F.S.B.*, 200 F.R.D. 164, 175 (E.D.N.Y. 2001) (question of fraudulent concealment is one common to all members of the class). Consequently, fraudulent concealment issues rarely “bar predominance satisfaction because those issues go to the right of a class member to recover, in contrast to underlying common issues of the defendant’s liability.” 2 CONTE & NEWBERG ON CLASS ACTIONS, § 4.26, at 241 (4th ed. 2002).

denied class certification only where the individual damages issues are especially complex or burdensome. *Smilow*, 323 F.3d at 40 and n.8; *In re IPO*, 2004 U.S. Dist. Lexis 20497, at \*169-70 (quoting *Humana*, 382 F.3d 1241). Although determining class damages may be “a laborious and time consuming task,” it is superior to the “staggeringly inefficient” approach of requiring each class member to prove adverse impact in individual proceedings, which “would provide countless opportunities for juries to render inconsistent verdicts” and present many individual Class members with a formidable, if not complete, cost barrier to recovery. *Id.*, at \*173-74.

**2. Individual damages will be calculated by using a standard formula and readily-available data**

While Phase II proposes an individualized procedure for determining damages, it does not present an intolerable burden. As described above, and contrary to Defendants’ assertion, Dr. Hartman will assess the amount of the illegal spread on a per drug basis, which will then serve as the yardstick for measuring individual damages in Phase II. Given that Class members will be able to identify each AWP-based payment from claims data and other documentation that is readily available,<sup>93</sup> application of a standard formula can be readily deployed to calculate specific damages. For the Medicare Part B Co-Pay Class, the information submitted will consist of documentation showing the amount of 20% co-pays made for AWPIDs. The Third-Party Payer and Co-Pay RICO Class members will submit contracts with PBMs and providers and claims data showing each reimbursement made for AWPIDs on the basis of AWP, along with the

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<sup>92</sup> See, e.g., *Terazosin*, 203 F.R.D. at 559 (“The fact the jury will also have to consider some individualized evidence in rendering individual damage calculations hardly precludes class certification.”); *In re Commercial Tissue Prod. Antitrust Litig.*, 183 F.R.D. 589, 596 (N.D. Fla. 1998) (“individual questions of damages are often encountered in antitrust actions, and they are rarely a barrier to certification”); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 522 (S.D.N.Y. 1996) (“Courts have allowed the plaintiffs to establish the measure of damages at trial, and this measure is then applied to the individual transactions (typically in a second bifurcated proceeding following trial on the common issues).”); *In re Catfish Antitrust Litig.*, 826 F. Supp. 1019, 1043-44 (N.D. Miss. 1993) (Individual damages questions are typical in class actions, rarely bar certification, and – if they did – “there would be little if any place for the class action device in the adjudication of antitrust claims.”); *In re Sugar Indus. Antitrust Litig.*, 73 F.R.D. 322, 354 (E.D. Pa. 1976) (If computing damages on an individual basis precluded certification, “it would be tantamount to encouraging wrongdoers to commit great antitrust violations on many consumers in small amounts so as to raise the spectre of unmanageability to defeat a class action.”).

<sup>93</sup> See App. 1(e); HRD at Section III.C, ¶ 22, pp. 27-30. Even Young has conceded that Class member claims data reveals the basis upon which *each* reimbursement was made and the amount of the reimbursement. See Young Decl., Ex. 17d.

reimbursement amount.<sup>94</sup> The specific damage calculations will be conducted through computer processing, permitting a level of automation and efficiency that Defendants simply ignore.

Thus, this case is readily distinguishable from Defendants' primary Texas authority, *Piggly Wiggly Clarksville, Inc. v. Interstate Brands Corp.*, 215 F.R.D. 523 (E.D. Tex. 2003), *aff'd*, 2004 U.S. App. Lexis 11160 (5th Cir. 2004), where the final price paid by class members varied greatly due to differences in the amount of product purchased, the geographic market, the particular services included with each purchase, and the skills of the particular negotiators. These factors made it "impossible to present evidence in a common manner as to the price each Plaintiff would have paid but for the alleged conspiracy." *Id.* at 531-32. Not so here, where *all* Class members paid based on the uniform AWP benchmark. Substituting the fraudulent AWP for what the non-fraudulent benchmark should have been – a "plug and play" formula – reveals the precise amount of damage on a transaction-by-transaction basis.<sup>95</sup> And as Dr. Hartman explains, the level of discounts or rebates negotiated is not relevant to this determination.<sup>96</sup>

### **C. Class Adjudication Remains the Superior Method of Resolving These Claims**

Defendants are not the first market players to cry that pricing in their industry is simply too complex to be evaluated and challenged in a large class action involving tens-of-thousands of would-be claimants. Indeed, invoking the shield of complexity is a time-honored tradition among participants in massive, nationwide industries. Fortunately for Plaintiffs, courts have routinely rejected arguments that the complexity and magnitude of an industry renders its participants immune from accountability for injuries that they have caused. The decisions are

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<sup>94</sup> HRD at Section III.C, ¶ 22, pp. 27-30.

<sup>95</sup> Defendants' other authorities, which appear in footnote 60 of their brief, are inapposite for similar reasons. *See Gibbs Props. Corp. v. Cigna Corp.*, 196 F.R.D. 430, 41 (M.D. Fla. 2000) (no standard formula could be applied to show common impact, not every class member was damaged, and damages would therefore have to be determined by an examination of each class member's underwriting file); *Arch*, 175 F.R.D. at 493 (no standard damage formula could be utilized due to individualized issues of addiction, causation, assumption of risk, consent and comparative fault); *Wilcox Dev. Co. v. First Interstate Bank, N.A.*, 97 F.R.D. 440, 447 (D. Or. 1983) (plaintiffs were unable to advance a mechanical method for litigating both injury in fact and class membership). And *Piggly Wiggly* is distinguishable on the additional basis that it relied in part on the Fifth Circuit's analysis in *Sandwich Chef*, which, as noted above, applies a standard that has been rejected by the First Circuit.

<sup>96</sup> HRD at Section IV.

legion in according class action status under such circumstances.<sup>97</sup> Drug pricing cases are no different.<sup>98</sup>

Litigation of this case in accord with Plaintiffs' Trial Plan would be superior to "clogging the federal courts with innumerable individual suits litigating the same issues repeatedly." *Humana*, 382 F.3d at 1273; *see also Carnegie*, 376 F.3d at 661 ("It would hardly be an improvement to have in lieu of this single class action 17 million suits ...."). Defendants have failed to identify any specific management problems that would render class treatment impracticable, aside from pointing out obvious complexities that are intrinsic to large commercial class actions.

Suggestions that a wrong is too extensive to be heard before a single court are "deeply disfavored in our society which is predicated upon the rule of law." *Chisolm*, 194 F.R.D. at 557; *see also Visa Check*, 280 F.3d at 140 (failing to certify on manageability grounds is disfavored and "should be the exception rather than the rule"). Therefore, "a class action has to be unwieldy ... before it can be pronounced an inferior alternative – no matter how massive the fraud or other wrongdoing that will go unpunished if class treatment is denied – to no litigation at all." *Carnegie*, 376 F.3d at 661. Denial of class certification "on the basis of vaguely perceived manageability obstacles is acting counter to the policy behind Rule 23" and unduly discounts the Court's "power and creativity in dealing with a class action flexibly as difficulties arise." *NASDAQ Antitrust Litig.*, 169 F.R.D. at 528. As the *Humana* court counseled, "[e]ven potentially severe management issues have been held insufficient to defeat class certification," and "we are not assessing whether this class action will create significant management problems, but instead determining whether it will create relatively more management problems than any of

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<sup>97</sup> A table summarizing those cases is attached hereto as Appendix A.

<sup>98</sup> *See Terazosin*, 203 F.R.D. at 559-60 (certifying class of direct purchasers of prescription drugs, finding that "defendants' assertions concerning the complexity of their pricing practices and other data used in the pharmaceutical industry do not persuade the Court that 'individual damage calculations will overwhelm the proceedings.' ... Complex industries, practices, or data are often examined in the course of class actions."); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 345 (E.D. Mich. 2001) (certifying class and commenting that "Defendants' attempt to characterize the market as too complex for common proof of injury is not unique"); *In re Brand Name Prescription Drugs Antitrust Litig.*, 1994 U.S. Dist. Lexis 16658, at \*11-12 (N.D. Ill. Nov. 15, 1994) (certifying class over defendants' objections that "the heterogeneous nature of 'brand name prescription drugs' presents an 'insuperable impediment' to a common proof of impact").

the alternatives (including, most notably, 600,000 separate lawsuits by the class members).” 382 F.3d at 1273. Notably, Defendants have not suggested a superior alternative for resolving these claims, and there is none.

As the decisions cited above highlight, courts are well equipped to manage complex class endeavors and should do so in the interests of justice. Indeed, the recent opinions in *Humana*, *Carnegie*, *Terazosin*, *IPO*, *Chisolm* and *Visa Check*, represent a trend – which transcends federal circuits – of putting forth the hard work necessary to try consumer and market pricing cases on a class-wide basis, notwithstanding the complexities that would arise. The Court should join that trend and certify this case and therefore provide a forum for the efficient adjudication of thousands of claims, many of which would never be brought for want of resources.<sup>99</sup> Plaintiffs and their experts have set forth a detailed and rational Trial Plan to manage this case on a class-wide basis, and Defendants have utterly failed to show that it cannot or should not be done.

DATED: December 17, 2004.

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<sup>99</sup> Defendants argue that the classes should not be certified because many large institutions could pursue individual cases. Defs. Br. at 48-49. But Aetna, Cigna, Blue Cross and the like have not sued these defendants for inflating AWP's on these particular drugs. Even if they had, the argument overlooks the many, many smaller health plans that would be easily outgunned by Defendants and their phalanx of defense counsel, as would individual consumers. See *In re WorldCom Inc. Sec. Litig.*, 219 F.R.D. 267, 305-06 (S.D.N.Y. 2003) (“Individual investors, small entities, and the many large investors who have not filed individual actions should not be deprived of their opportunity to pursue this action simply because some larger litigants with greater financial resources are presently pursuing parallel actions.”).

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**CERTIFICATE OF SERVICE**

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF CLASS CERTIFICATION** to be electronically filed with the Court pursuant to the December 16, 2005 Order and to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 17, 2004, a copy to Verilaw Technologies for Posting and notification to all parties

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